

PTO/SB/08A (07-05)

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet	1	of	6	Attorney Docket Number	021819-000130US
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**Complete if Known**

Application Number	10/780,114
Filing Date	February 17, 2004
First Named Inventor	Dow, Steve W.
Art Unit	1633
Examiner Name	Anne Marie Sabrina Wehbe

**U.S. PATENT DOCUMENTS**


Examiner Initials*	Cite No.	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number Kind Code <sup>2</sup> (if known)			
AW	AA	US-4,957,735	09/18/1990	Huang	
	AB	US-5,013,556	05/07/1991	Woodie, et al.	
	AC	US-5,043,164	08/27/1991	Huang, et al.	
	AD	US-5,399,346	03/21/1995	Anderson, et al.	
	AE	US-5,580,859	12/03/1996	Felgner, et al.	
	AF	US-5,589,466	12/31/1996	Felgner, et al.	
	AG	US-5,593,972	01/41/1997	Weiner, et al.	
	AH	US-5,641,662	06/24/1997	Debs, et al.	
	AI	US-5,643,578	07/01/1997	Robinson, et al.	
	AJ	US-5,663,153	09/02/1997	Hutcherson, et al.	
	AK	US-5,676,954	10/14/1997	Brigham	
	AL	US-5,679,647	10/21/1997	Carson, et al.	
	AM	US-5,686,101	11/11/1997	Tagawa, et al.	
	AN	US-5,693,622	12/02/1997	Wolff, et al.	
	AO	US-5,703,055	12/30/1997	Felgner, et al.	
	AP	US-5,703,057	12/30/1997	Johnston et al.	
	AQ	US-5,705,187	01/06/1998	Unger	
	AR	US-5,705,385	01/06/1998	Bally, et al.	
	AS	US-5,723,335	03/03/1998	Hutcherson, et al.	
	AT	US-5,817,856	10/06/1998	Tirosh, et al.	
	AU	US-5,820,873	10/13/1998	Choi, et al.	
	AV	US-5,827,703	10/27/1998	Debs, et al.	
	AW	US-5,830,878	11/03/1998	Gorman, et al.	
	AX	US-5,976,567	11/02/1999	Wheeler, et al.	
	AY	US-5,981,501	11/09/1999	Wheeler, et al.	
	AZ	US-6,121,247	09/19/2000	Huang, et al.	
	BA	US-6,194,388 B1	02/27/2001	Krieg, et al.	
	BB	US-6,207,646 B1	03/27/2001	Krieg, et al.	
	BC	US-6,224,901 B1	05/01/2001	Li, et al.	
	BD	US-6,239,116 B1	05/29/2001	Krieg, et al.	
	BE	US-6,287,591 B1	09/11/2001	Semple, et al.	
	BF	US-6,339,068 B1	01/15/2002	Krieg, et al.	
	BG	US-6,406,705 B1	06/18/2002	Davis, et al.	
	BH	US-6,534,484 B1	03/18/2003	Wheeler, et al.	
	BI	US-6,589,940	07/2003	Raz, et al.	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Kind Codes of U.S. Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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			Application Number	10/780,114	
			Filing Date	February 17, 2004	
			First Named Inventor	Dow, Steve W.	
			Art Unit	1633	
Examiner Name	Anne Marie Sabrina Wehbe				
Attorney Docket Number	021819-000130US				
Sheet	2	of	6		

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
AW ↓	BJ	US-6,627,615 B1	09/30/2003	Debs, et al.	
	BK	US-US2002/0110586 A1	08/15/2002	Madden, et al.	
	BL	US-US2002/0119990 A1	08/29/2002	Madden, et al.	
	BM	US-US2003/0082228 A1	05/01/2003	Flowers, et al.	
	BN	US-			

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
AW 	BO	PCT	WO94/04196	A1	03/03/1994	Imperial Cancer Research Technology Limited		<input type="checkbox"/>
	BP	PCT	WO93/25673	A1	12/23/1993	The Regents of the University of California		<input type="checkbox"/>
	BQ	EP	0819758	A2	01/21/1998	James Archibald Mixson		<input type="checkbox"/>
	BR							<input type="checkbox"/>
	BS							<input type="checkbox"/>

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Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
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				Examiner Name	Anne Marie Sabrina. Wehbe
Sheet	3	of	6	Attorney Docket Number	021819-000130US

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	BT	VERMA, Inder M., et al. "Gene Therapy - promises, problems and prospects", <i>Nature</i> (1997) 389:239-242	<input type="checkbox"/>	
	BU	ORKIN, Stuart H., et al. "Report and Recommendation of the Panel to Assess the NIH Investment in Research on Gene Therapy", (1995) 1-41	<input type="checkbox"/>	
	BV	RAZ, E., et al. "Cationic Lipids Inhibit Intradermal Genetic Vaccination", <i>Vaccines</i> (1994) 94:71-75	<input type="checkbox"/>	
	BW	GAO, Xiang "Cationic Lipid-Based Gene Delivery: An Update", (undated) pp 99-112	<input type="checkbox"/>	
	BX	RODMAN, David M., et al. "Delivery of Genes Through the Lung Circulation", (undated) Chapter 9, pp. 181-191	<input type="checkbox"/>	
	BY	FREIMARK, Bruce D., et al. "Cationic Lipids Enhance Cytokine and Cell Influx Levels in the Lung Following Administration of Plasmid: Cationic Lipid Complexes", <i>J. Immunology</i> (1998) 160:4580-4586	<input type="checkbox"/>	
	BZ	YAMAMOTO, Toshiko, et al. "Lipofection of Synthetic Oligodeoxyribonucleotide Having a Palindromic Sequence of AACGTT to Murine Splenocytes Enhances Interferon Production and Natural Killer Activity", <i>Microbiol. Immunol.</i> (1994) 38(10):831-836	<input type="checkbox"/>	
	CA	BALLAS, Zuhair K., et al. "Induction of NK Activity in Murine and Human Cells by CpG Motifs in Oligodeoxynucleotides and Bacterial DNA", <i>Journal of Immunology</i> (1996) 157:1840-1845	<input type="checkbox"/>	
	CB	KRIEG, Arthur M. "Lymphocyte activation by CpG dinucleotide motifs in prokaryotic DNA", <i>Trends in Microbiology</i> (1996) 4(2):73-77	<input type="checkbox"/>	
	CC	PISETSKY, David S. "The Immunologic Properties of DNA", <i>The Journal of Immunology</i> (1996) 156:421-423	<input type="checkbox"/>	
	CD	SATO, Yukio, et al. "Immunostimulatory DNA Sequences Necessary for Effective Intradermal Gene Immunization", <i>Science</i> (1996) 273:352-354	<input type="checkbox"/>	
	CE	STACEY, Katryn J., et al. "Macrophages Ingest and Are Activated by Bacterial DNA", <i>The Journal of Immunology</i> (1996) 157:2116-2122	<input type="checkbox"/>	
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Sheet	4	of	6	Attorney Docket Number	021819-000130US

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
AW	CF	SUN, Siquan, et al. "Dual Function of Drosophila Cells as APCs for Native CD8 <sup>+</sup> TCells: Implications for Tumor Immunotherapy", <i>Immunity</i> (1996) 4:555-564	<input type="checkbox"/>	
	CG	LIU, Yong, et al. "Factors influencing the efficiency of cationic liposome-mediated intravenous gene delivery", <i>Nature Biotechnology</i> (1997) 15:167-173	<input type="checkbox"/>	
	CH	LEITNER, Wolfgang W., et al. "DNA and RNA-based vaccines: principles, progress and prospects" <i>Vaccine</i> (2000) 18:765-777	<input type="checkbox"/>	
	CI	LESOON-WOOD, Leslie A., et al. "Systemic Gene Therapy with p53 Reduces Growth and Metastases of a Malignant Human Breast Cancer in Nude Mice", <i>Human Gene Therapy</i> (1995) 6:395-405	<input type="checkbox"/>	
	CJ	OKAMOTO, T., et al. <i>Proceedings of the American Association for Cancer Research</i> (1997) 38: Abstract #78	<input type="checkbox"/>	
	CK	LI, Xiu-Min, et al. "Mucosal IFN- $\lambda$ Gene Transfer Inhibits Pulmonary Allergic Responses in Mice", <i>The Journal of Immunology</i> (1996) 157:3216-3219	<input type="checkbox"/>	
	CL	McLEAN, John W., et al. "Organ-specific endothelial cell uptake of cationic liposome-DNA complexes in mice", <i>American Journal of Physiology</i> (1997) 273:H3878-H404	<input type="checkbox"/>	
	CM	PISETSKY, David S. "Immune Activation by Bacterial DNA: A New Genetic Code", <i>Immunity</i> (1996) 5:303-310	<input type="checkbox"/>	
	CN	ROMAN, Mark, et al. "Immunostimulatory DNA sequences function as T helper -1- promoting adjuvants", <i>Nature Medicine</i> (1997) 3(8):849-854	<input type="checkbox"/>	
	CO	ROSENBERG, Steven A., et al. "Regression of Established Pulmonary Metastases and Subcutaneous Tumor Mediated by the Systemic Administration of High-dose Recombinant Interleukin 2", <i>J. Exp. Med.</i> (1985) 161:1169-1188	<input type="checkbox"/>	
	CP	SCHEULE, Ronald K., et al. "Basis of Pulmonary Toxicity Associated with Cationic Lipid-Mediated Gene Transfer to the Mammalian Lung", <i>Human Gene Therapy</i> (1997) 8:689-707	<input type="checkbox"/>	
↓	CQ	TEMPLETON, Nancy S., et al. "Improved DNA: liposome complexes for increased systemic delivery and gene expression", <i>Nature Biotechnology</i> (1997) 15:647-652	<input type="checkbox"/>	

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AW	CR	GREGORIADIS, Gregory, et al. "Liposome-mediated DNA vaccination", <i>FEBS Letters</i> (1997) 402:107-110	<input type="checkbox"/>	
	CS	NAITOH, J., et al. <i>Proceedings of the American Association for Cancer Research</i> (1998) 39: Abstract #2421	<input type="checkbox"/>	
	CT	HO, Rodney J.Y., et al. "Interactions of Target-sensitive Immunoliposomes with Herpes Simplex Virus", <i>Journal of Biological Chemistry</i> (1987) 262(29):13979-13984	<input type="checkbox"/>	
	CU	HO, Rodney J.Y., et al. "Target-sensitive Immunoliposomes as an Efficient Drug Carrier for Antiviral Activity", <i>Journal of Biological Chemistry</i> (1987) 262(29):13973-13978	<input type="checkbox"/>	
	CV	HO, Rodney J.Y., et al. "Target-sensitive Immunoliposomes: Preparation and Characterization", <i>Biochemistry</i> (1986) 25:5500-5506	<input type="checkbox"/>	
	CW	ALLEN, T.M., et al. "Large unilamellar liposomes with low uptake into the reticuloendothelial system", <i>FEBS Letters</i> (1987) 223(1):42-46	<input type="checkbox"/>	
	CX	KLIBANOV, Alexander L. "Amphipathic polyethyleneglycols effectively prolong the circulation time of liposomes", <i>FEBS Letters</i> (1990) 268(1):235-237	<input type="checkbox"/>	
	CY	WOODLE, Martin C., et al. "Sterically stabilized liposomes", <i>Biochimica et Biophysica Acta</i> (1992) 1113:171-199	<input type="checkbox"/>	
	CZ	CORNELIE, S., et al. "Methylated cpG-Containing Plasmid Activates the Immune System", <i>Scandinavian Journal of Immunology</i> (2004) 59:143-151	<input type="checkbox"/>	
	DA	SASAKI, Shin, et al. "Adjuvant formulations and delivery systems for DNA vaccines", <i>Methods</i> (2003) 31:243-254	<input type="checkbox"/>	
	DB	C.J. WHEELER, et al. "A novel cationic lipid greatly enhances plasmid DNA delivery and expression in mouse lung", <i>Proc. Natl. Acad. Sci. USA</i> (1996) 93:11454-11459	<input type="checkbox"/>	
	DC	LIU, Y, et al. "Cationic Liposome-mediated intravenous Gene Delivery", <i>J. Biol. Chem.</i> (1995) 270(42):24864-24870	<input type="checkbox"/>	

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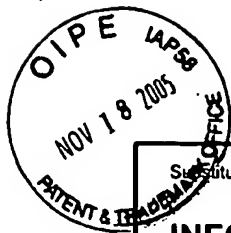
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	DD	ZOU, Yiyu, et al. "Effective Treatment of Early Endobronchial Cancer With Regional Administration of Liposome-p53 Complexes", <i>J. Natl. Cancer. Inst.</i> (1998) 90(15):1130-1137	<input type="checkbox"/>
	DE	OUDRHIRI, Noufissa, et al. "Gene transfer by guanidinium-cholesterol cationic lipids into airway epithelial cells <i>in vitro</i> and <i>in vivo</i> ", <i>Proc. Natl. Acad. Sci. USA</i> (1997) 94:1651-1656	<input type="checkbox"/>
	DF	STRIBLING, Roscoe, et al. "Aerosol gene delivery <i>in vivo</i> ", <i>Proc. natl. Acad. Sci. USA</i> (1992) 89:11277-11281	<input type="checkbox"/>
	DG	NABEL, Gary J., et al. "Direct gene transfer with DNA-liposome complexes in melanoma: Expression, biologic activity, and lack of toxicity in humans", <i>Proc. Natl. Acad. Sci. USA</i> (1993) 90:11370-11311	<input type="checkbox"/>
	DH	LI, Daqing, et al. "Combination Surgery and Nonviral Interleukin 2 Gene Therapy for Head and Neck Cancer", <i>Clinical Cancer Research</i> (1999) 5:1551-1556	<input type="checkbox"/>
	DI	PHILIP, Ramila, et al. "In Vivo Gene Delivery", <i>J. Biol. Chem.</i> (1993) 268(22):16087-16090	<input type="checkbox"/>
	DJ	HIROAKI, Hemmi, et al. <i>Nature Immunology</i> (2002) 3(2): 196-200	<input type="checkbox"/>
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PTO/SB/08A (08-03)

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Sheet	1	of	1	Attorney Docket Number	021819-000130US

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AW	AA	US-2003/0022854 A1	01/30/2003	Dow, et al.	
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		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
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	BB							<input type="checkbox"/>

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